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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/646,454	08/21/2003	William F. Kiesman	A085 CON	9532
1473	7590 06/14/2005		EXAMINER	
FISH & NEAVE IP GROUP			BERCH, MARK L	
ROPES & GRAY LLP 1251 AVENUE OF THE AMERICAS FL C3			ART UNIT	PAPER NUMBER
NEW YORK	, NY 10020-1105		1624	
			DATE MAILED: 06/14/2005	

Please find below and/or attached an Office communication concerning this application or proceeding.

····		Application No.	Applicant(s)					
Office Action Summary		10/646,454	KIESMAN ET AL.					
		Examiner	Art Unit					
		Mark L. Berch	1624					
Period fo	The MAILING DATE of this communication a or Reply	ppears on the cover sheet with the o	correspondence address					
THE I - Exter after - If the - If NO - Failu Any I	ORTENED STATUTORY PERIOD FOR REP MAILING DATE OF THIS COMMUNICATION asions of time may be available under the provisions of 37 CFR of SIX (6) MONTHS from the mailing date of this communication. period for reply specified above is less than thirty (30) days, a reperiod for reply is specified above, the maximum statutory period to reply within the set or extended period for reply will, by state eply received by the Office later than three months after the mailed patent term adjustment. See 37 CFR 1.704(b).	I. I.136(a). In no event, however, may a reply be tireply within the statutory minimum of thirty (30) days d will apply and will expire SIX (6) MONTHS from the cause the application to become ABANDONE	mely filed ys will be considered timely. the mailing date of this communication. ED (35 U.S.C. § 133).					
Status								
1)🖂	Responsive to communication(s) filed on 03	<i>May 2005</i> .						
2a)⊠	This action is FINAL . 2b)⊠ This action is non-final.							
3)	Since this application is in condition for allowance except for formal matters, prosecution as to the merits is							
	closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.							
Dispositi	on of Claims							
4)🖂	4)⊠ Claim(s) <u>1-6,11,39,41 and 42</u> is/are pending in the application.							
	4a) Of the above claim(s) is/are withdrawn from consideration.							
5)	5) Claim(s) is/are allowed.							
6)⊠ —	Claim(s) <u>1-6,11,39,41 and 42</u> is/are rejected.							
_	Claim(s) is/are objected to.							
8)	8) Claim(s) are subject to restriction and/or election requirement.							
Applicati	on Papers							
9)🛛	The specification is objected to by the Examir	ner.						
10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.								
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).								
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).								
11) 🗌 🗀	The oath or declaration is objected to by the E	Examiner. Note the attached Office	Action or form PTO-152.					
Priority u	nder 35 U.S.C. § 119							
	Acknowledgment is made of a claim for foreign All b) Some * c) None of: 1. Certified copies of the priority document 2. Certified copies of the priority document 3. Copies of the certified copies of the priority document copies of the certified copies of the priority document copies of the certified copies of the priority document copies of the certified copies of the priority document copies of the certified copies of the priority document copies of the certified copies of the priority document copies of the certified copies of the priority document copies of the certified copies of the priority document copies of the certified copies of the priority document copies of the certified copies of the priority document copies of the certified copies of the priority document copies of the certified copies of the priority document copies of the certified copies of the priority document copies of the certified copies of the priority document copies of the certified copies of the ce	nts have been received. Ints have been received in Applications or ity documents have been received.	ion No					
• •	application from the International Bure							
* See the attached detailed Office action for a list of the certified copies not received.								
Attachment	(s)							
	e of References Cited (PTO-892)	4) Interview Summary	· ·					
	e of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Da	ate Patent Application (PTO-152)					
	nation Disclosure Statement(s) (PTO-1449 or PTO/SB/08 No(s)/Mail Date	6) Other:	αιστι πρριισαυτί (Γ 10~132)					

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DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-6, 11, 39, 41-42 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The two new choices for R5 are new matter. The original formula was wrong, but applicants have not shown that one of ordinary skill in the art would have been sure that this new choice was what was intended. The original choice was attached via a sulfur. One could have retained attachment by a sulfur just by switching the "3" to a "2". There is no way of knowing whether that choice, or the one which was actually selected, was what was really intended, and hence this choice is new matter.

Claims 1-6, 11, 39, 41-42 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- 1. The "traumatic brain damage of claim 41 is not a disease. It is a condition. Suggested is "...from a disease or condition".
- 2. The "sulfoxy" in "sulfoxyacyl" and as a substituent on aryl is rendered indefinite by the remarks. A monovalent group that ends in "...oxy" is bound via an oxygen. See e.g. 5384176 and note structures on front page. But the structure that applicants use in the remarks, taken from the specification, is attached via a sulfur. Thus, it is not clear what the claims intend.
- 3. Claims 41-42 no longer have any actual step in them. These originally depended on claim 40, but when claims 41-42 were made independent, the actual step from claim 40 was not carried into the claims.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

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Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-6, 11, 39, 41-42 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and others of U.S. Patent No. 6649600. Although the conflicting claims are not identical, they are not patentably distinct from each other because there is extensive overlap with the claims of the parent. For example, if R3 is option a) and is unsubstituted, then there is overlap (even with claim 11). Also, note that in the b) list of substituents for option a), applicants have retained the R5-alkylsulfonyl and R5-alkylthio, but these were in the parent patent as well.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-4, 6, and 39, 41 are rejected under 35 U.S.C. 103(a) as being unpat99entable over Suzuki '782, WO 94/16702, Suzuki et al (1992), or Shimada et al (1992).

In Suzuki '782, see examples 29 (no linker) and 11 (methylene linker). In WO 04/16702, see compound G and E. In Shimada et al (1992), see 44 and 45. In Suzuki et al (1992), see 22 and 23. These show the adamantyl compound, with or without methylene

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linker. Applicants have the same, except that the adamantyl has a methyl group stuck on. Compounds that differ only by the presence or absence of an extra methyl group or two are homologues. Homologues are of such close structural similarity that the disclosure of a compound renders prima facie obvious its homologue. As was stated in In re Grose, 201 USPQ 57, 63, "The known structural relationship between adjacent homologues, for example, supplies a chemical theory upon which a prima facie case of obviousness of a compound may rest." The homologue is expected to be preparable by the same method and to have generally the same properties. This expectation is then deemed the motivation for preparing homologues. Of course, these presumptions are rebuttable by the showing of unexpected effects, but initially, the homologues are obvious even in the absence of a specific teaching to add or remove methyl groups. See In re Wood, 199 USPQ 137; In re Hoke, 195 USPQ 148; In re Lohr, 137 USPQ 548; In re Magerlein, 202 USPQ 473; In re Wiechert, 152 USPQ 249; Ex parte Henkel, 130 USPQ 474; Ex Parte Fischer 96 USPQ 345; In re Fauque, 121 USPQ 425; In re Druey, 138 USPQ 39. In all of these cases, the close structural similarity between two compounds differing by one or two methyl groups was itself sufficient show obviousness. See also MPEP 2144.09, second paragraph.

Further, the feature of a methyl group attached to the 8-position substituent is seen in example 5 of Suzuki '782.

Note that in the parent, this rejection was overcome by the removal of the tricyclic group option, but this has been retained in the instant claim 1.

The traverse is unpersuasive. Applicants point out, correctly, that the claims have a substituent, e.g. methyl whereas the prior art compounds are unsubstituted. That is correct, but that just means that the claims are not anticipated. Applicants refer to the

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"structural non-obviousness" but do not present reasoning why adding the methyl group is not structurally obvious. Applicants refer to their "demonstrated utility", but having a utility is not evidence of unobviousness.

Specification

The abstract is objected to as incomplete. The essence of the invention is in R3, which is not defined. Suggested is the abstract used in the parent.

The specification is objected to as having numerous typographical errors. These were noted in the Certificate of correction as presented in the parent; these need to be fixed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark L. Berch whose telephone number is 571-272-0663. The examiner can normally be reached on M-F 7:15 - 3:45.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on (571)272-0661. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Mark L. Berch Primary Examiner Art Unit 1624

6/9/05